REMARKS

I. Examiner's Response to Arguments and Allowable Subject Matters

Applicants acknowledge the Examiner's indication that Claims 11, and 17-20 are now added back into prosecution and that Claims 17-20 are allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Applicants reserve amending Claims 17-20 to independent form in view of the arguments presented below which Applicants believe will overcome all outstanding rejections and objections.

Applicants further acknowledge the Examiner's withdrawal of the rejections of Claim 24 under 35 U.S.C. §112.

With respect to the Examiner's comments on the objection to the drawings, 35 U.S.C. 102(e) rejection based on Cauthen (U.S. Patent No. 6,454,806), 35 U.S.C. 103 rejection based on Cauthen and Gauchet et al. (U.S. Patent No. 6,733,532), Applicants will address them in the appropriate sections below.

II. Drawings Objections and 35 U.S.C. §112 Rejections

Reconsideration is requested of the Examiner's objection under 37 C.F.R. 1.83(a) that the drawings fail to show the "supplemental support" of Claims 13-15, 38 and 39 and of the Examiner's rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for "supplemental support" of Claims 13-15, 38 and 39. The "supplemental support" of Claims 13-15, 38 and 39 has been amended to read "additional stabilizing assembly," which is the "additional stabilization" referenced on page 8, lines 18-21 in the Specification and the "connecting and stabilizing assembly 35" of Fig. 11A and the description related thereto clearly showing such "additional stabilizing assembly" in the form of "clamping plate 36," "connecting rods 38," and "screws." Specification, p.18, lines 7-21.

Although as noted by the Examiner that the Specification is directed to Fig. 11A and not Fig. 16 of the elected embodiment, Applicants respectfully point the Examiner to the "Summary of Invention" wherein Applicants intended, and as would be understood by one skilled in the art, that different features of the different embodiments are to be applied to the different embodiments. The specification supports such a reading because although different embodiments are shown, the specification describes all the embodiments as the "present invention" and describes the features as applicable to all these embodiments. See, e.g., Summary of Invention, p.6, line 8 – p.7, line 16 (emphasis added):

> SUMMARY OF INVENTION
>
> **The present invention is an inter-space artificial disc implant utilized to replace a damaged disc.** The present invention is clearly an improvement over the prior art providing an implant prosthesis intrinsically participating in this fusion process, self-stabilizing to the spinal segments, consistent with conventional methods of disectomy and uniquely and novel consistent with the preservation of the integrity of the adjacent vertebrae and their functionality.
>
> The **present invention** comprises an artificial disc implant for the purpose of which is to aid in and directly cause bone fusion at the bearing endplate surface portions of said device following the removal of a damaged disc. Said prostheses are biocompatible, structurally load bearing devices, stronger than bone, capable of withstanding the forces generated within the spinal inter-space. The bearing endplate surfaces have a plurality of openings of specific size which can be filled with fusion promoting material by inducing bone growth and osseous integration with the adjacent vertebrae forming a bony bond to the implants and each other. The implant bone-contacting surface may be textured, designed or otherwise treated by any known technologies to enhance and achieve bone in-growth and fusion to the implant's endplates to enhance stability of the implant and to expedite the fusion. The improved devices are configured and designed so as to promote their own stability within the vertebral inter-space to resist dislodgment, prevent micro-motion and stabilize the adjacent vertebrae.
>
> The **present implant** is made of a biocompatible material and has means if desired for increasing osseous integration, controlling hemostasis and preventing infection and controlling pain. It establishes proper spinal curvature or lordosis and kyphosis and capable of reducing a vertebral listness (a forward or backward translation of one vertebrae upon another as well as lateral misalignment of said vertebrae). It gives increased safety and precision which provides complete and easy visualization of the structures involved and adjacent vital structures (e.g. organs, neural structures and blood vessels and related bony

surfaces). It also eliminates the need for a second surgical procedure to harvest bone. It also provides the method and material that is bio-resorbable and bio-compatible for **additional means of stabilization to be used in conjunction with the implant artificial disc prosthesis for certain conditions that require additional stabilization for osseous integration**. It may be used in distraction osteogenesis procedures in order to increase bone length and/or for inducing bone growth and osseous integration of the implant, and for controlling hemostasis and pain and preventing infection during and following the surgical procedure allowing for an increased opportunity of success.

Therefore, in reading the patent specification as a whole, one of ordinary skill in the art would understand that the "additional stabilizing assembly" of Fig. 11A would be applicable to the different embodiments in the specification, whether it is a spinal cage of Fig. 1, Fig. 10, Fig. 12, Fig. 13, etc. or a spinal disc of Fig. 16. As indicated in the "Brief Description of the Drawing" section of the specification: "Although the invention has been described with regard to the preferred embodiments, it is recognized that other embodiments of the present invention may be devised which would not depart from the scope of the present invention." Therefore, Fig. 11A is an illustrative example of the "additional stabilizing assembly," which enables one skilled in the art of the subject matters of Claims 13-15, 38 and 39.

The section called "Procedure for Implant" (Specification, p.7, line 18 – p. 9, line 4) further supports this position:

> PROCEDURE FOR IMPLANT
>
> A conventional disectomy is performed and the vertebral end plates are roughened in preparation for use of the implant prosthesis of the present invention.
>
> In an anterior cervical device implantation a short transverse incision is made across the front of the neck and off-center, preferably to the right of the midline and directly over the diseased or otherwise disc being replaced. The platysma muscle is dissected and split and the sternocleido-mastoid muscle with the carotid sheath is protected and retracted laterally. The esophagus, trachea and associated midline structures are protected and retracted medially, thus exposing the anterior aspect of the cervical spine. The disc involved is identified and removed by known, acceptable and conventional surgical methods. The adjacent vertebral end plates are gently scraped free of any remaining cartilage until diffuse fine punctuate decortication is achieved. The dimensions of the inter-space are then measured in mild distraction and compared with

the stereo-tactic pre-surgical x-ray diagnostic procedures and video imaging devices which helps to determine the exact intra-discal space to be restored relative to the vertebrae involved and the undamaged disc space that exists inferiorly and superiorly to the vertebrae involved. **The appropriate device or devices are selected for insertion** with a specially designed device that establish the necessary space for insertion behind the anterior lips of the vertebrae. The device is activated for establishing the desired inter-vertebral space and said device is locked at the desired height. Alternatively, the prosthesis may be a single, double or multiple activated device so as to properly provide stability and the proper curvature or lordosis of the spine. Harvested bone or bone fill material commonly employed is packed into and around the implant. Alternatively a new bone fill material is provided that is a polymer capable of being polymerized into a desired shape and size via being a resorbable biocompatible photo-initiated polymer and cured via visible light. **In certain situations of trauma and disease additional stabilization is required and a resorbable biocompatible photo-initiated polymer rod or plate and screws may be utilized and to be attached to the vertebrae involved as well as healthy vertebrae above and below the damaged site. Guide plates are provided for drilling holes to affix the plate and or rod to the vertebrae with the necessary screws. In extreme cases the additional stabilization may employ currently available rigid devices for such purposes.** All areas are inspected and the wound is then closed in the routine manner. A further biocompatible resorbable photo-initiated polymer is provided to control hemostasis as well as controlling post-operative pain or infection. The devices may also be used in other areas of the spine, such as the thoracic and lumbar regions, utilizing both the anterior or posterior surgical approaches as selected by the surgeon.

The Examiner apparently did not consider this position previously presented in the last filed Amendment because the Examiner did not address why one of ordinary skill in the art would not understand that different features (e.g. "additional stabilizing assembly" of Fig. 11A) are applicable to all the embodiments (e.g. Fig. 16) described in the patent specification. Therefore, in view of the above, Applicants believe the drawing requirement under 37 C.F.R. 1.83(a) and the enablement requirement under 35 U.S.C. 112, first paragraph are complied with.

III. 35 U.S.C. §102 (Cauthen)

Reconsideration is requested of the Examiner's rejection of Claims 1-5, and 11-13 under 35 U.S.C. 102(e) as being anticipated by Cauthen, U.S. Patent No. 6,019,792. The Examiner relied on the Cauthen reference for disclosing all the elements of Claim 1, relied on element 90 in

Fig. 5 as the "flexibly and compressibly" flexible supporting means, and interpreted the "plate members" of Claim 1 broadly.

A claim is anticipated under 35 U.S.C. §102(e) only if "**each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). Amended Claim 1 discloses an artificial disc for placement between adjacent vertebrae comprising:

> at least ***one upper substantially flat plate member and one lower substantially flat plate member***, each plate member having ~~a~~ corresponding outer and inner bearing surfaces;
> at least one flexible supporting means interposed between said upper and lower plate members and abutting said corresponding inner bearing surfaces, ***said flexible support means flexibly and compressibly supporting said upper and lower plate members to allow compression of the adjacent vertebrae***; and
> at least one means for stabilizing said flexible supporting means for a certain period of time to allow at least two of said outer bearing surfaces to osteo-integrate with the adjacent vertebrae.

The Cauthen reference fails to disclose, teach or suggest at least the above elements of amended Claim 1 as shown in ***bold and italics*** above. The term "plate member" of the claims has been amended to read "substantially flat plate member," which patentably distinguishes them from the hemicylindrical elements of the Cauthen reference. Contrary to the Examiner's position that "applicant's [sic] specification does not use nor support the term 'plate member'," Applicants respectfully direct the Examiner to page 13, lines 11-18 of the Specification (emphasis added):

> Referring to the embodiment of Fig. 16, a flexible spinal fusion prosthesis is shown in which **upper and lower plate members 100 and 101** are provided with an intermediate convex flexible disc 102 interposed therebetween. The disk 102 may be made of titanium or some other known material which is biocompatible and compressible. A rigid collar 103 of resorbable material surrounds the disc 102 to make the flexible disc 102 rigid in order to allow integration of the **upper and lower plate members 100 and 101** with the

> bones of the vertebrae. The collar 103 will be resorbed and thereafter the flexible disc 102 will function in a flexible manner between the vertebrae.

The substantially flat plate members of the present invention advantageously provide the required surface area to contact the adjacent vertebrae and to allow the plate members to osteo-integrate with adjacent vertebrae and distribute loads to the spine and all three planes of motion, namely, axial, saggital and coronal or any combination of the three planes. The hemicylindrical elements of the Cauthen reference do not provide for even distribution of loads placed upon the spine and in most cases two hemicylindrical elements are required for an even distribution of the load forces placed upon the spine. As shown in Fig. 4A of the Cauthen reference, the hemicylindrical element is seated deeply into the vertebral endplates and body and requires special surgical preparation of the vertebral endplates by drilling, boring and tapping of said endplates. It has been documented that such a surgical procedure may at times result in the subsidence of the device thereby disadvantageously decreases the intervertebral space. Furthermore, the hemicylindrical elements of the Cauthen reference provides a circular or oval contact with adjacent vertebrae, and are patentably distinct from and inferior to the substantially flat plate members of the present invention.

Further, the Cauthen reference discloses an articulating spinal implant comprises two hemicylindrical elements with a ball-and-socket joint between the two elements that resists axial compression and allows pivotal movement:

> An articulating ball-and-socket joint between the two elements **resists compression** and lateral movement between the vertebrae .... Abstract (emphasis added).

> In a further preferred embodiment, the joint surfaces are formed as engaging concave and convex surfaces to create a ball-and-socket type joint, which allows relative pivotal motion between the vertebrae, but **resists compression therebetween**. Col. 2, line 66 – Col. 3, line 3 (emphasis added).

> The first and second articulation surfaces **resist axial compression between the first and second elements in the direction of the support axis**, but allow relative pivotal motion between the first and second elements. Col. 3, lines 23-27 (emphasis added).
>
> The second element includes a second articulation surface, wherein the first and second articulation surfaces adjoin to form a joint allowing relative pivotal movement between the first and second elements but **preventing relative compression between the first and second elements**. Col. 3, lines 42-46 (emphasis added).
>
> **The articulation means 24 resists axial compression** between the first and second elements 20, 22, but allows relative pivotal movement therebetween. Thus, when implanted, as shown in Fig. 4, the articulation means 24 **resists axial compression between first and second vertebra 12, 14 along a support axis 44** extending generally along the spinal column, as shown in Fig. 4, but permits pivotal movement between vertebrae. Col. 5, lines 9-17 (emphasis added).
>
> **Axial compression, as well as lateral translation normal to the support axis 44, is resisted** between the first and second vertebrae 12, 14, by providing the first internal articulation surface 40 with a void .... Col. 5, lines 25-28 (emphasis added).
>
> The articulating spinal implant used to carry out this method is preferably substantially similar to the example embodiment described above, having first and second internal articulation surfaces which adjoin to form a joint allowing relative pivotal movement between the first and second elements, but **preventing relative axial compression therebetween**. Col. 7, lines 61-67 (emphasis added).
>
> **The implant resists axial compression between the first and second elements**, and thereby prevents relative compression between the first and second vertebrae, thus maintaining the desired intervertebral space. Col. 9, lines 12-14 (emphasis added).

The repeated references to the resistance of axial compression undermines the Examiner's position and reliance on a hemispherical bowl-shaped cap 90 that is "**somewhat** resilient to absorb implant loading" as compressible (Col. 7, lines 39-42 (emphasis added)). The Cauthen reference clearly teaches a device that **resists axial compression** and **against a device that allows axial compression**. In relying on his position that the cap 90 of the Cauthen device allows axial compression, the Examiner failed to address this apparent conflicting teachings of the Cauthen reference. It is clear to one skilled in the art that the modifying term "somewhat" for the "resilient" cap 90 of the Cauthen reference provides for the consistent teaching of resisting

axial compression as taught by the Cauthen reference. The Cauthen reference has a resorbable end cap or end section that joins the two hemicylindrical elements adjacent to the vertebra to form a solid cylindrical shape. The rigid resorbable collar around the interposed flexible support as shown in Fig. 16 of the present invention does not join the upper and lower plate members adjacent to the vertebra. Furthermore, the flexible support of the present invention allows for slight rotation when the rigid collar is in place whereas the device of the Cauthen reference does not allow for rotation when the rigid resorbable end cap is in place.

Applicants believe that it is advantageous to provide an artificial disk that compresses with minimal pivotal movement. The flexible supporting means of the present invention advantageously compresses, as shown in Fig. 16 and discussed in the Specification, p.13, lines 13-14 (**The disk 102** may be made of titanium or some other known material which is **biocompatible and compressible**) (emphasis added). The relative thickness and size of disc 102 with respect to the plate members provide sufficient compression of the artificial disc with minimal relative pivotal movement of the plate members. Throughout the specification, the Cauthen reference teaches against a compressible spinal implant and repeatedly stresses the importance of resisting axially compression of the spinal implant. Therefore, the Cauthen reference intentionally fails to teach "each and every element" of amended claim 1 and all claims dependent therefrom, as required under a §102(e) rejection.

IV. 35 U.S.C. §103 (Cauthen in view of Shinn)

Reconsideration is requested of the Examiner's rejection of Claims 24 and 14-15, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, in view of Shinn et al., U.S. Patent No. 5,683,465. The Examiner relied on the Cauthen reference for disclosing all the elements of the rejected claims and admitted that the Cauthen reference

failed to disclose a "substance with anti-microbial drug eluting factors" and relied on the Shinn reference for disclosing this element.

As argued in §III, supra, the Cauthen reference fails to disclose, teach or suggest all the elements of amended Claims 1 and 12. Similarly, the Shinn reference also does not disclose, teach or suggest a "***said flexible support means flexibly and compressibly supporting said upper and lower plate members to allow compression of the adjacent vertebrae***" of the present invention. Therefore, amended Claim 1, and all claims dependent therefrom, are not unpatentable over the Cauthen reference in view of the Shinn reference.

V. 35 U.S.C. §103 (Cauthen in view of Gauchet)

Reconsideration is requested of the Examiner's rejection of Claims 4, and 6-7 under 35 U.S.C. 103 as being unpatentable over Cauthen, U.S. Patent No. 6,019,792, in view of Gauchet et al., U.S. Patent No. 6,733,532. The Examiner relied on the Cauthen reference for disclosing all the elements of the rejected claims and admitted that the Cauthen reference failed to disclose a "flexible disc [having] opposed convex surfaces" and relied on the Gauchet reference for disclosing this element.

Applicants respectfully submit that the Gauchet reference is not a proper prior art under a 35 U.S.C. 103 rejection because the priority date of the Gauchet reference is not before the critical date of the present invention.

The critical date of the present invention is July 26, 1999, based on the following priority: the present invention is a division of Serial No. 10/072,163, filed February 7, 2002 (now issued as U.S. Patent No. 6,719,796), which is a continuation of Serial No. 09/360,796, filed July 26, 1999 (now issued as U.S. Patent No. 6,454,806). Therefore, this application is given the earlier filing date of Patent No. 6,454,806, which is **July 26, 1999**.

On the other hand, the priority date of the Gauchet reference is as follows:

Date	Event
Dec. 11, 1998	Filing date of French application – "Date de depot"
June 16, 2000	Date of laying open of French application / date published in France – "date de mise a la disposition du public de la demande"
Dec. 9, 1999	PCT Filed
June 22, 2000	PCT Publication Date
July 20, 2001	§371(c)(1),(2),(4) Date
May 11, 2004	Date of US Patent

A foreign patent "should not be cited as a reference until its date of patenting or publication can be confirmed by an examiner's review of a copy of the document." M.P.E.P. §901.05. When a U.S. Patent is being cited as a reference, and it claims the priority of a foreign application, it is necessary to determine when the foreign application issued or published. Id; See, M.P.E.P. §2126.01 ("The date the patent is available as a reference is generally the date that the patent becomes enforceable"); Chisum, Patents §3.06[4].

The determination of whether a foreign patent has been issued or the application was published can be found using the table provided in Section 901.05V of the M.P.E.P. The table provides that in France the date of laying open the application is the earliest possible reference date. M.P.E.P. §901.05V. See, Duplan Corp. v. Deering Milliken, Inc., 353 F.Supp. 826, 833, 176 U.S.P.Q. 432 (D.S. 1973), aff'd, 487 F.2d 459, 179 U.S.P.Q. 449 (4th Cir. 1973); M.P.E.P. §2127 III ("The contents of a foreign patent application should not be relied upon as prior art until the date of publication can be confirmed by an examiner's review of a copy of the document").

Using the translations provided on the M.P.E.P. chart, along with Gauchet's French Patent 98 15672, a copy of the cover page is attached hereto, the date of laying open is **June 16,**

2000, which is after the priority date of the present invention, **July 26, 1999**. Because the information in the Gauchet reference was not available to the public until June 16, 2000, it would not have been obvious to one skilled in the art at the time of the filing of the present invention to utilize the opposed convex surfaces configuration. Therefore, the Gauchet reference cannot be cited as a prior art reference under a §103 rejection and it is improper to combine the Cauthen and Gauchet references and it would not be obvious to one skilled in the art to utilize the opposed convex surfaces configuration taught by the Gauchet reference in the device of the Cauthen reference.

Further, as discussed in §III, supra, the Cauthen reference intentionally teaches a spinal implant that resists axial compression. However, the Gauchet reference discloses a prosthesis that compresses. The prostheses disclosed in the Cauthen and Gauchet references are distinct in purpose and structure and cannot be combined in a §103 rejection because one reference teaches something against what the other reference teaches. There is no suggestion or motivation in either reference to modify the device to provide or not provide compression of the other reference other than hindsight obtained after reading Applicants' specification. Therefore, it is improper, under M.P.E.P. §706.02(j) to combine the Cauthen and Gauchet references and it would not be obvious to one skilled in the art to utilize the opposed convex surfaces configuration taught by the Gauchet reference in the device of the Cauthen reference.

VI. New Claims

New Claims 43-45 are added to clarify the scope of the present invention.

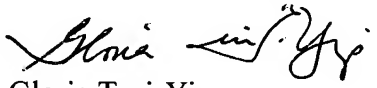
VII. Conclusion

Applicants respectfully request that this Amendment be entered because it requires only a cursory review by the Examiner, does not raise issue of new matter nor requires additional search.

If the Examiner has any questions on the above and believes a telephone conference will aid in the allowance of the application, please contact the undersigned by telephone.

By virtue of the Applicants' amendment to the specification and claims and remarks thereto, all outstanding grounds of rejection and objection have been addressed and dealt with and, based thereon, it is believed that the application is now in condition for allowance and such action is respectfully solicited.

Respectfully submitted,



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(71) Demandeur(s) : *DIMSO (DISTRIBUTION MEDICALE DU SUD-OUEST) Société anonyme* — FR.

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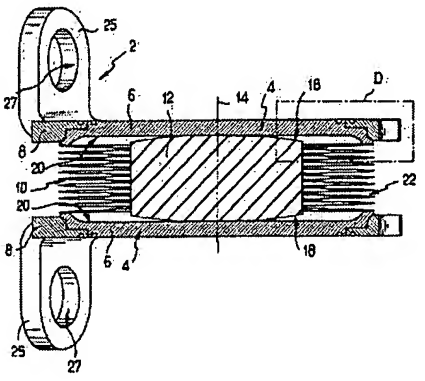
(54) PROTHESE DE DISQUE INTERVERTEBRAL A COMPORTEMENT MECANIQUE AMELIORE.

(57) La prothèse de disque intervertébral comporte deux plateaux (4) et un coussin (10) interposé entre les plateaux, le coussin comportant un corps compressible (12) présentant des extrémités (18) en contact avec les plateaux (4). Au moins l'une des extrémités (18) est libre de se déplacer par rapport au plateau associé suivant une direction parallèle au plateau.



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